

## **REMARKS**

### **I. Status of the Application**

Claims 1-7, 10-11, and 13-26 are pending in the present application. Claims 8-9 and 12 have been previously cancelled. Claims 1-7, 10-11, and 13-26 stand rejected under 35 U.S.C. § 112, first paragraph, for the addition of new matter. Claims 2-7, 10-11, 13-14, and 20-26 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1-7, 10-11, 13-14, and 20-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over US 5,480,436 to Bakker et al. (hereinafter “Bakker ‘436”) in view of WO 01/10478 and US 2002/0095213 A to Bakker et al. (hereinafter “Bakker ‘213”). Claims 1-7, 10-11, and 13-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bakker ‘213 in view of Bakker ‘436, US 5,980,948 to Goedemoed et al. (hereinafter “Goedemoed”), WO 01/10478, or EP 0 830 859.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants’ novel invention. Specifically, claim 1 has been amended to delete the term “apparatus” and instead to recite a medical device. Support for this amendment can be found throughout the specification as filed, for example from page 4, line 29 to page 5, line 26. Claim 1 has also been amended to delete the term “polymeric materials.” Claims 2-7, 10-11, 13-15, and 22-24 have been amended to delete the term “coating” and instead to recite a medical device. As the Examiner admits, a medical device is taught throughout the specification. Claims 10 and 11 have been amended to delete the term “additive.” Claim 17 has been amended to recite the biologically active agent of claim 18, so claim 18 has been cancelled. Claim 20 has also been cancelled. Claim 21 has been amended to correct dependency to claim 1, and also to delete the term “adhesion of tissues.” Claim 26 has been amended to delete the term “collagen.”

Thus, the amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

## **II. Interview Summary**

Applicants are grateful to the Examiner for granting a telephone interview on August 8, 2006. Applicants inquired as to the allowability of the pending claims if independent claim 1 were to be amended to delete the term “polymeric materials.” The Examiner agreed that this claim amendment would overcome the 35 U.S.C. § 103(a) rejections of the instant Office Action if dependent claims 13 and 21 were also amended to delete recited medical devices that are known in the art to be made only of polymeric materials. Accordingly, the term “collagen” has been deleted from claim 26, which depends from claim 21.

Applicants respectfully submit that all the recited medical devices of claims 13 and 21 can have a surface being a material selected from the group consisting of metals, metal alloys, ceramics, and glasses. For example, metal catheters are known in the art (see Attachment A [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\\_uids=9030350&dopt=Abstract](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9030350&dopt=Abstract)). Metallic non-woven fabrics are also known (e.g. gold foil implant, see Attachment B <http://www.orthopedictechreview.com/issues/feb00/pg20.htm>). Vascular grafts made of metal are also known (see US 4,441,215). Cardiac patches with metal components are also known (see metallic struts in the intracardiac septal defect occlusion device of US 5,451,235). Implants which contain medicinal products, having metal, ceramic, and/or glass components, are also known (see US 6,491,666). Thus, the recited medical devices of claims 13

and 21 have proper antecedent basis in the recited surface materials of claim 1. Accordingly, Applicants respectfully request allowance of claims 1-7, 10-11, and 13-26.

### **III. Claims 1-7, 10-11, and 13-26 Do Not Recite New Matter**

At page 2, second paragraph of the instant Office Action, claims 1-7, 10-11, and 13-26 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that the recited apparatus in claim 1 is new matter. Applicants respectfully traverse the rejection. Claim 1 has been amended to delete the term “apparatus” and instead claims a medical device comprising a surface and a coating applied to the surface of the medical device. Support for a medical device with a coating applied to its surface can be found throughout the specification as filed, for example from page 4, line 29 to page 5, line 26. Therefore, independent claim 1 and its dependent claims present no new matter. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph rejection and allowance of claims 1-7, 10-11, and 13-26.

### **IV. Claims 2-7, 10-11, 13-14, and 20-26 Are Definite**

At page 2, fifth paragraph of the instant Office Action, claims 2-7, 10-11, 13-14, and 20-26 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection.

Claim 1 has been amended to recite a medical device instead of an apparatus. Dependent claims 2-7, 10-11, 13-14, and 22-24 have been amended to also recite a medical device. Claim 20 has been cancelled and dependent claims 21, 25, and 26 already recite a medical device.

Also, claims 10 and 11 have been amended to delete the term “additive.” Thus, all the dependent claims have proper antecedent basis.

Claims 18 and 20 have been cancelled, thus removing redundancy. The recited medical device of claims 21, 25, and 26 does further limit the recited medical device of amended claim 1. Claim 21 has been amended to delete the recited “adhesion of tissues.”

For the above reasons, all pending claims are definite. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection and allowance of claims 2-7, 10-11, 13-14, and 20-26.

**V. Claims 1-7, 10-11, 13-14, and 20-26 Are Not obvious over Bakker ‘436 in View of WO 01/10478 and Bakker ‘213**

At page 3, fourth paragraph of the instant Office Action, claims 1-7, 10-11, 13-14, and 20-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bakker ‘436 in view of WO 01/10478 and Bakker ‘213. Applicants respectfully traverse the rejection.

Claim 1, from which all other claims depend, has been amended to delete the recited “polymeric materials” from the group of surface materials. Bakker ‘436 discloses a copolymer coated on another layer of copolymer, but fails to teach the recited copolymer coated on metal, metal alloy, ceramic, or glass. Nor does Bakker ‘436 suggest the desirability of coating a copolymer on any material other than a polymer. WO 01/10478 and Bakker ‘213 both fail to remedy the deficiencies of Bakker ‘436. Neither WO 01/10478 (directed to preparing a solid body of polymer by gel molding) nor Bakker ‘213 (directed to prosthetic devices formed from polymer) teaches the recited copolymer coated on the recited surface materials. Bakker ‘213 discloses various implant coatings as examples of prosthetic devices formed from polymer (page 6, paragraph [0075]). However, Bakker ‘213 does not teach or suggest the surface materials of

the implants upon which the coating is applied. None of the references suggests that the recited copolymer would have good adhesion as a coating on the variety of different surface materials recited in claim 1. Thus, the skilled artisan would not be motivated to combine and modify the references to use the recited copolymer in combination with a biologically active agent as a coating for metals, metal alloys, ceramics, and glasses.

A *prima facie* case of obviousness cannot be made because the references fail to teach or suggest each and every claim limitation, and also fail to provide motivation to combine and modify their teachings to arrive at the claimed subject matter with a reasonable expectation of success. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1-7, 10-11, 13-14, and 20-26.

**VI. Claims 1-7, 10-11, and 13-26 Are Not Obvious over Bakker ‘213 in View of Bakker ‘436, Goedemoed, WO 01/10478, or EP 0 830 859**

At page 4, fourth paragraph of the instant Office Action, claims 1-7, 10-11, and 13-26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bakker ‘213 in view of Bakker ‘436, Goedemoed, WO 01/10478, or EP 0 830 859. Applicants respectfully traverse the rejection.

Claim 1, from which all other claims depend, has been amended to delete the recited “polymeric materials” from the group of surface materials. As discussed in section IV above, Bakker ‘213 fails to teach or suggest the recited copolymer coated on metal, metal alloy, ceramic, or glass. Bakker ‘436, Goedemoed, WO 01/10478, and EP 0 830 859 all fail to remedy the deficiencies of Bakker ‘213. Neither Bakker ‘436 (directed to a device made of two layers of polymer), Goedemoed (directed to a drug delivery matrix made of copolymer microspheres), WO 01/10478 (directed to preparing a solid body of polymer by gel molding), nor EP 0 830 859

(directed to a drug delivery matrix made of copolymer similar to Goedemoed above) teaches the recited copolymer coated on the recited surface materials. None of the references suggests that the recited copolymer would have good adhesion as a coating on the variety of different surface materials recited in claim 1. Thus, the skilled artisan would not be motivated to combine and modify the references to use the recited copolymer in combination with a biologically active agent as a coating for metals, metal alloys, ceramics, and glasses.

A *prima facie* case of obviousness cannot be made because the reference fails to teach or suggest each and every claim limitation, and also fail to provide motivation to combine and modify their teachings to arrive at the claimed subject matter with a reasonable expectation of success. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1-7, 10-11, and 13-26.

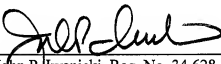
## VII. Conclusion

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

Dated: August 8, 2006

By



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